Validating the PSR13 as a Measure of Perceived Postoperative Recovery Following Laparoscopic Sacrocolpopexy

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Financial Disclosures: None

Financial Support: None.

Single sentence summary: A patient-reported measure of post-operative recovered was validated in women undergoing laparoscopic sacrocolpopexy for pelvic organ prolapse.

This is the author's manuscript of the article published in final edited form as:

Carpenter, J. S., Heit, M., Chen, C. X., Stewart, R., Hamner, J., & Rand, K. L. (2017). Validating the Postdischarge Surgical Recovery Scale 13 as a Measure of Perceived Postoperative Recovery After Laparoscopic Sacrocolpopexy. Female Pelvic Medicine & Reconstructive Surgery, 23(2), 86–89. https://doi.org/10.1097/SPV.0000000000000352

ABSTRACT

Objectives: No postoperative recovery measurement tools have been validated among women undergoing laparoscopic sacrocolpopexy for pelvic organ prolapse, which impedes development and testing of strategies to improve recovery. The purpose of this study was to evaluate the performance of the Post-discharge Surgical Recovery Scale (PSR) as a measure of perceived recovery in laparoscopic sacrocolpopexy patients.

Methods: Women (N=120) with ≥ stage 2 pelvic organ prolapse undergoing laparoscopic sacrocolpopexy completed a 15-minute postoperative survey (days 7, 14, 42, and 90 (each ± 3 days)) that included the15-item PSR. A confirmatory factor analysis was conducted using data from 14 days post-surgery, when patients would have begun to recover, but there was likely to be substantial variability in recovery across patients. We also assessed validity and explored sensitivity to change over time and minimally important difference values.

Results: Confirmatory factor analysis indicated a good fitting model for a reduced version of the PSR (i.e., PSR13). Regressions showed that the PSR13 prospectively predicted single-item recovery scores. PSR13 recovery significantly improved from Day 7 to 42 suggesting the PSR13 is sensitive to change. Descriptive statistics including minimally important differences are reported. The minimally important difference was estimated to be around 5 points.

Conclusion: The PSR13 is a psychometrically sound tool for measuring recovery over time in this population. Its short length makes it an ideal postoperative recovery measure in clinical practice or research.

KEY WORDS: Female, outcome assessment (health care), psychometrics, post-operative recovery, laparoscopic sacrocolpopexy

INTRODUCTION

Surgical recovery is a process that typically occurs over a span of weeks as patients heal and rest at home.[1] It is an important patient-reported outcome to consider in research and clinical practice as a marker of a patient's perception of their ability to return to pre-surgical functioning and quality of life. Despite its importance, there is no single, measure that is widely used across studies. In one systematic review, there were as many different generic recovery measures (n=7) as there were studies conducted (n=7).[2] In subsequent reviews, 11 and 12 different recovery assessment tools were identified that varied in item content, scoring, and timing of assessment.[3,4]

One theoretically based and carefully tested scale for general surgery patients is the Post-discharge Surgical Recovery Scale (PSR) developed by Kleinbeck.[5] Based on Leventhal's[6] self-regulation theory, recovery is conceptualized and measured as the degree to which an individual perceives they have returned to pre-illness physiological, functional, and social states. PSR items were developed based on literature review, clinician expertise, and semi-structured interviews with 19 post-operative endoscopic cholecystectomy outpatients. Response options vary but all are semantic differential scales (e.g., better to worse) rated from 0 to 100. Higher scores indicate better recovery. The PSR was tested and validated in a cross-sectional study of general surgery patients. Exploratory factor analysis showed that the final 15-item scale consisted of a single factor. It was highly correlated with a single item of perceived global surgical recovery, had high content validity as judged by experts, and internal consistency of 0.88.[5] When rated against 8 published criteria for quality assessment, the PSR received positive ratings for 4 criteria and was the only one of 12 instruments reviewed without floor or ceiling effects.[4]

Despite these promising results, the PSR has not been sufficiently tested to justify its use as a patient-reported outcome measure in other surgical populations or in clinical trials designed

to optimize recovery after surgery. We found no published information on the PSR's sensitivity to change over time or minimally important differences (MID) estimates in any population. Because we needed a psychometrically sound measure of perceived recovery in a planned intervention study focusing on laparoscopic sacrocolpopexy patients, the purpose of our study was to conduct additional psychometric testing in our population of interest: laparoscopic sacrocolpopexypatients. We built upon the prior psychometric testing by performing confirmatory factor analysis and data reduction, validity testing, and exploring sensitivity to change and MIDs.

MATERIALS AND METHODS

This was a descriptive, prospective, longitudinal study of patients' perceived recovery after laparoscopic sacrocolpopexy on postoperative days 7, 14, 42, and 90 (± 3 days). The study was approved by the institutional review board and all patients provided informed consent and authorization to use protected health information.

Inclusion criteria were: women with ≥ stage 2 pelvic organ prolapse undergoing laparoscopic sacrocolpopexy, who felt competent responding to web-based surveys, had a reliable internet connection at home, and self-reported understanding English at an 8th grade reading level.

Procedures were as follows. The surgeon and/or research nurse approached eligible candidates after their preoperative surgical consultation visit and provided them with a study information sheet describing the nature and scope of the research project, the requirements for study participation, the time commitment involved, the minimal risks, potential benefits and alternatives to study participation. Potential participants were given adequate time to review the information and ask questions before deciding about the study. Eligible and interested

participants provided written, informed consent, were scheduled for surgical repair, and then asked to complete a 15 minute private and secure (HIPAA-compliant) web-based survey delivered by Research Electronic Data Capture (REDCap).[7]

Measures

Baseline socio-demographic and pre-operative clinical data included patient age at the time of surgery, body mass index, (BMI), race, the Hollingshead four-factor index of socio-economic status (SES score), prolapse stage, marital status, educational level, and number of prior abdominal/pelvic surgeries.

The 15-item PSR was used as the measure of patients' perceived postoperative recovery. Because it was administered via computer, for each item, participants were presented a visual analogue slider scale coded from 0 to 100 to represent the left and right anchors.[5] The purpose of anchors is to provide narrative examples to help interpret the response categories. The exact wording of the anchors varied across items. Study participants were asked to move the slider along the continuous scale to indicate the extent to which the anchor word described their experience. The coding of responses from 0 to 100 eliminated the need to convert the total scores from a 10 to 100 point scale after averaging the scores from the 15 individual items.

Patients also completed a single-item measure of perceived global surgical recovery (GSR) at each time point similar to the one used in the original PSR testing.[5] The GSR item asked: "If 100% recovery is back to your usual health, what percentage of recovery are you now?" Participants responded using a visual analogue slider scale from 0 to 100.

Data Analysis

REDCap[7] provided automated export procedures for seamless data downloads to common statistical packages. Confirmatory factor analyses (CFA) were conducted using

LISREL 8.80[8] and data from the second time point (14 days post-surgery) because patients would have begun to recover from their surgeries, but there was likely to be substantial variability in recovery across patients. We began by fitting the model reported in the original PSR manuscript.[5] If the model showed poor fit or other model-related problems, we planned to revise it accordingly until we achieved a good-fitting model. Several indices were used to assess model fit: (1) the Root Mean Square Error of Approximation (RMSEA, good fit ≤ 0.08) and its 90% confidence interval; (2) the Comparative Fit Index (CFI, good fit ≥ 0.95); (3) the Non-Normed Fit Index (NNFI, good fit ≥ 0.95); and (4) the Standardized Root Mean Residual (SRMR, good fit ≤ 0.08)[9]. We also report the model chi-square statistic (χ^2, good fit $p > 0.05$).

For the revised scale, we calculated descriptive statistics and Cronbach's alpha (internal consistency reliability). Validity was assessed using correlations between PSR and GSR scores at each time point and multiple regressions with PSR scores predicting future time single item GSR score. MIDs were established by distribution-based methods. Specifically, we calculated the standard error of measurement (SEM=SD * square root (1-reliability)), which reflects the smallest difference or change score likely to reflect a true difference rather than measurement error.[10] We chose SEM as the MID estimate over effect size MIDs because SEM incorporates both effect size and scale reliability, and therefore is less likely to change across different populations.[10]

RESULTS

A total of 134 patients consented to participate at baseline (pre-surgery), with 125 (93.3%) completing measures at 7 days post-surgery, 120 (89.6%) at 14 days post-surgery, 112 (83.6%) at 42 days post-surgery, and 87 (64.9%) at 90 days post-surgery. Sample characteristics at baseline are shown in Table 1. Participants were an average age of 63 years old (range 37 to

79), non-Hispanic white women, with a history of 1-2 abdominal surgeries, and scheduled for laparoscopic sacrocolpopexy.

A total of 120 patients completed post-operative measures at 7 days post-surgery. Missingness on the PSR at Time 2 ranged from 0% to 3.33%. Because of the small proportion of missing data, we treated them as missing at random and used PRELIS 2.8 to impute missing values using the expectation-maximization algorithm. Our check of normality assumptions showed that two items showed restriction of range, with most patients indicating they were not experiencing problems. For item 2 (Alertness), 54.2% of participants responded with a 0 out of 100 (0 indicating being alert) and 72.5% responded with a 20 or lower out of 100. For item 14 (Ability to Care for Self), 31.2% responded with a 0 out of 100 (0 indicating being able to care for themselves) and 87.5% responded with a score of 20 or lower out of 100. Given these responses, we dropped these two items before further analyses. None of the remaining 13 items were excessively skewed (> 3.0) or kurtotic (> 10.0).[11]

Confirmatory Factor Analysis

As shown in Table 2, a one-factor model showed mixed evidence of fit to the 13 PSR items. The modification indices suggested that the error terms for the following should be correlated (1) items 4 (Level of energy) and 7 (Level of sleepiness) and (2) items 1 (Overall versus what you thought you would be feeling) and 15 (Overall feeling of normalcy). We decided that correlating these was reasonable given their conceptual and wording similarities and the new one-factor model showed good fit to the data. Moreover, this model fit the data significantly better than the initial model. The standardized factor loadings of each of the 13 items are presented in Table 3. We continued to investigate this reduced PSR, hereafter called the PSR13 (total scores range from 0-100 (greater recovery)).

Reliability and Validity

The scale showed strong internal consistency reliability (Cronbach's alphas = 0.91-0.93).For validity, PSR-GSR correlations ranged from r = .695 at 7 days to r = .338 at 90 days post-surgery (all $p < .001$). Regression results indicated PSR scores predicted future GSR scores: (1) PSR13 scores at 7 days predicted GSR scores at 14 days, $\beta = 0.379$, $p < .001$, but not at 42 days or 90 days; (2) PSR13 scores at 14 days predicted GSR scores at 42 days, $\beta = 0.283$, $p = .004$, but not at 90 days, and (3) PSR13 scores at 42 days predicted GSR at 90 days, $\beta = 0.296$, $p = .007$.

Sensitivity to Change and MIDs

Descriptive statistics and MIDs on the PSR13 based on the Standard Error of the Mean (SEM) are shown in Table 4. The MID was estimated to be around 5 points. Recovery scores significantly increased from baseline to 42 days, with the greatest recovery change occurring between 14 and 42 days post-surgery. There was no significant change in recovery between 42 and 90 days. At 90 days post-surgery, 38% of patients had a PSR13 score above 90.

DISCUSSION

A patient's perception of post-operative recovery is an important indicator of health-related quality of life[5] and this study was designed to further measurement of this important patient-reported outcome. Our first major finding was that a reduced PSR13 was a psychometrically sound measure for assessing perceived recovery when tested in a sample of post-laparoscopic sacrocolpopexy women. Given the short length of PSR-13, and it may be easy to incorporate into clinical practice. MIDs can help providers to determine whether a patient's perceived recovery state has changed, and determine whether an intervention supporting

recovery has been successful. Based on our findings, providers can consider a 5-point change in PSR scores to be clinically meaningful.

It is notable that correlations between the PSR13 and GSR were similar to those observed by Kleinbeck using the PSR15 and alternative global recover item.[5] In this study, we extended Kleinbeck's[5] prior work by reducing the scale through confirmatory factor analyses, further establishing validity, documenting its sensitivity to change over time, and establishing MIDs using distribution-based methods. MIDs are useful in powering equivalence or non-inferiority trials[12] as well as interpreting results of cross-sectional or longitudinal studies. Our work responded to Kluivers et al's[4] recommendations regarding the need to further validate the PSR through application in longitudinal clinical studies with a focus on both sensitivity to change and MIDs. These recommendations[4] were based on the fact that the scale has only been tested in the immediate post-operative phase.[5] Although future research will be needed to determine whether our MIDs generalize to other post-surgical populations, our analyses help justify use of the PSR13 in clinical research, particularly intervention studies among the laparoscopic sacrocolpopexy population.

A second notable finding relates to the conceptualization and measurement of recovery. Based on the factor loadings, the strongest indicators of recovery centered around activity levels, including work and exercise (items 5, 11, 12) as well as global appraisals of recovery (items 4, 13). Interestingly, specific problem areas (e.g., pain, sleepiness, bowel functioning) were weaker indicators of recovery. These findings may indicate that (1) patients perceive their recovery status based on resuming normal life activities rather than on the presence of specific symptoms, (2) that activity measures such as pedometers or actigraphy may be appropriate additional or alternative measures of recovery, and (3) that interventions that promote a quicker return to

normal life activities may be highly valued by women during the post-operative recovery period. It will be important to test these hypotheses in future research. A future study could be used to evaluate the relationship between the PSR13 and objective measures of activity (pedometers, actigraphy) and compare their sensitivity to intervention effects.

A third notable finding relates to the trajectory of recovery over time. Recovery scores at each time point were highly predictive of subsequent recovery and most patients were nearly fully recovered by 42 days (6 weeks). The extent to which this trajectory relates to recovery expectations set by health care professionals is unclear. Participants' scores may have reflected the belief that they "should" have felt recovered by 42 days.

Our study findings should be interpreted in the context of our study limitations. The study sample was relatively large but from a single institution and with limited racial and ethnic diversity. A gold standard for measuring recovery does not exist so our comparisons are only to a global item as was done in the original psychometric testing[5] and not a gold standard. Because we did not include a time point between 14 and 42 days, we may have missed important variation in the trajectory of recovery occurring between these dates. Our study sample was limited to women undergoing one type of pelvic floor surgery and results may not be generalizable beyond laparoscopic sacrocolpopexy patients. It will be important to test the PSR13 in other pelvic floor surgical populations to evaluate its psychometric properties.

In conclusion, our study findings support use of the PSR13 as a measure of postoperative recovery in laparoscopic sacrocolpopexy patients. Findings also raise questions and hypotheses to be tested in future research.

ACKNOWLEDGEMENTS

None.

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